Antishock Garment

Technology Opportunity Assessment

Prepared for the Merck for Mothers Program
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Summary

If a woman with obstetric hemorrhage progresses into shock, she is likely to suffer serious injury or die without advanced treatment. In low-resource settings, where specialized care may be hours or even days away, health providers need a reliable, inexpensive way to stabilize patients until help is available. The nonpneumatic antishock garment, or NASG, is gaining wide acceptance as a simple and effective option. Continued development, advocacy, and research can increase uptake of the NASG, saving women’s lives worldwide.

Statement of need

Obstetric hemorrhage is estimated to cause 25% of all maternal deaths and is the leading direct cause of maternal mortality worldwide. Postpartum hemorrhage (PPH), defined as vaginal bleeding in excess of 500 mL after delivery, accounts for most cases of obstetric hemorrhage. It occurs in more than 10% of all births and is associated with a 1% case fatality rate.

Although active management of the third stage of labor (AMTSL) can prevent up to 60% of PPH cases, PPH continues to have a devastating impact on women in low-resource settings. Obstetric hemorrhage accounts for 34% of maternal deaths in Africa, 31% in Asia, and 21% in Latin America and the Caribbean. Among women who do survive PPH, approximately 12% will have severe anemia. Also, women who survive severe PPH (greater than 1,000 mL of blood loss) are significantly more likely to die during the following year.

AMTSL is recommended by the World Health Organization (WHO) and is endorsed by the International Federation of Obstetricians and Gynecologists (FIGO) and the International Congress of Midwives for the prevention of PPH. The three components of AMTSL are prophylactic uterotonics, controlled cord traction, and uterine massage. Although the effectiveness of AMTSL has been well documented, it poses some challenges and limitations in low-resource settings. Even when it is performed exactly, AMTSL prevents only 40% to 50% of PPH caused by uterine atony. In severe cases of intractable uterine atony, bleeding will not respond to the administration of uterotonics. Also, AMTSL does not treat shock, a dangerous progression of PPH. If PPH-related shock is not treated immediately, she can die of hypovolemic shock or suffer irreparable damage to vital organs.

Definitive treatment of PPH-related shock and PPH unresponsive to uterotonics can only occur in comprehensive emergency medical obstetric care (CEmOC) facilities, but health providers must be first able to stabilize the patient enough for referral. In cases where other treatment options are unsuccessful or
practitioners are not sufficiently skilled, the last resort is to perform an emergency hysterectomy, leaving the woman unable to have more children.

In short, to save lives when medical management fails to control PPH and a CEmOC is not immediately available, health providers need a simple, low-cost, and effective intervention that will reduce blood loss, reverse the effects of shock, and stabilize patients. The nonpneumatic antishock garment (NASG) may meet this need.

Technology solutions landscape

Over the last decade, new research, funded by the Bill & Melinda Gates Foundation, the John D. and Catherine T. MacArthur Foundation, and the National Institutes of Health, has indicated that the NASG can control PPH bleeding, reverse shock, and stabilize patients experiencing PPH so that they can be safely transported for further medical care.

The NASG is a lightweight neoprene garment that resembles the bottom half of a wetsuit. It was developed in the early 1970s by the National Aeronautics and Space Administration as a modification of the inflatable pneumatic antishock garment (PASG). The NASG is simpler in design than the PASG, more quickly and easily applied, less expensive, and avoids the risk of overinflation and excessive pressure. Because it is also lighter and more flexible than the PASG, a woman can “wear” it more easily and for longer periods of time, which is often necessary in low-resource settings where conditions require lengthy transport. Whereas the PASG is bulky and obscures the perineum, the design of the NASG permits complete perineal access, allowing health providers to place urinary catheters, suture genital lacerations, perform speculum or bimanual examinations, and provide manual vacuum aspiration or uterine exploration or curettage. Thus, the source of much obstetrical bleeding can be located and repaired while the garment remains in place, stabilizing vital signs.

Much like the PASG, the NASG functions by providing circumferential counter pressure to the lower body in order to shunt blood from the lower extremities and abdominal area to the essential core organs: heart, lungs, and brain. The garment’s five neoprene segments close tightly with Velcro around the legs, pelvis, and abdomen to supply from 20 to 40 mmHg of circumferential pressure. The abdominal segment incorporates a small foam pressure ball to provide uterine compression. In addition to reversing shock and stabilizing the patient, circumferential pressure decreases both the transmural pressure and the radius of uterine, abdominal, and other lower-body arteries. According to the physics of blood flow as expressed by LaPlace’s law, Poiseuille's law, and Bernoulli’s principles, reduction in arterial transmural pressure and radius results in decreased blood flow.

The NASG is ideal for low-resource settings because it can be washed and reused at least 40 times. Additional attributes that make this an appropriate technology for developing countries are ease of use, minimal required training, and portability—it can be easily carried to outlying areas.
Pilot studies have shown that the NASG can decrease obstetric hemorrhage and stabilize a patient until proper medical treatment is available. Use of the NASG has been reported in a study of 634 women with obstetric hemorrhage (43% with uterine atony) in Egypt. Women treated with a NASG had a median blood loss that was on average 200 mL lower (range 300–100 ml lower) than women who received standard treatment. However, there have been no completed randomized controlled trials (RCTs) on the use of the NASG in the treatment of PPH. A randomized cluster trial is under way in Zambia and Zimbabwe to examine whether early application of a NASG by midwives prior to transfer to a referral hospital can decrease death and injury. Additional recent hemodynamic flow and pressure studies suggest a significant increase in internal iliac artery flow resistance with NASG application and provide a physiological explanation of how the NASG might reduce PPH.

Clinical trials in Egypt, Nigeria, Mexico, Zambia, and Zimbabwe were conducted using the original NASG (model). That garment is currently sold in the United States and around the world. To introduce a more affordable model in low-resource settings, PATH recently negotiated affordable, high-quality NASG manufacturing with a qualified Chinese manufacturer and distributor (Blue Fusion Group, Hong Kong) who can supply the NASG for approximately $60 (not including shipping). Additional efforts are under way to establish small NASG production by early 2013. Bench-level testing has demonstrated that the original and Blue Fusion garments are substantially equivalent in elasticity, durability, Velcro strength, dimensions, and other key attributes.

Recent 2012 progress on the NASG includes:

- Completion of the RCTs.
- Completion of a meta-analysis that synthesized the findings from five NASG studies conducted at tertiary care facilities.
- Inclusion of the NASG in the WHO 2012 guidelines for prevention and treatment of PPH.
- Inclusion in 2012 FIGO guidelines.

The NASG is not a one-size-fits-all garment. Three sizes (small, medium, and large) have been developed to accommodate differences in women’s bodies worldwide (population-dependent anthropomorphic variation).

Table 1, below, illustrates the cost-effectiveness of the NASG when compared to several other PPH treatment methods. If proven effective, the device will be very competitive with other methods of PPH treatment. Furthermore, the NASG is unique among the group of comparison treatments in that it treats shock. This provides an additional benefit when other treatments have not been available or have failed and conditions have escalated to become life threatening.

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* This comparison assumes the NASG is proven effective for treating PPH. Note that a pivotal study is currently in progress.
Table 1. Cost-effectiveness and cost-benefit analysis of curative interventions for postpartum hemorrhage.*

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Total DALYs Averted (000)</th>
<th>Total Benefit of Intervention ($000)</th>
<th>Total Cost of Intervention ($000)</th>
<th>Cost per DALYs Averted ($)</th>
<th>Cost-Benefit Ratio</th>
<th>Ranking by DALYs Averted</th>
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<tr>
<td>Balloon tamponade</td>
<td>6,461</td>
<td>$10,608,929</td>
<td>$6,452</td>
<td>$1</td>
<td>1,644.21</td>
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<td>Antishock garment</td>
<td>6,023</td>
<td>$9,889,227</td>
<td>$13,896</td>
<td>$2</td>
<td>711.65</td>
<td>2</td>
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<td>Oxytocin in Unject™ injection system***</td>
<td>4,037</td>
<td>$6,628,359</td>
<td>$26,097</td>
<td>$6</td>
<td>253.99</td>
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<td>Syntometrine</td>
<td>4,417</td>
<td>$7,252,100</td>
<td>$38,872</td>
<td>$9</td>
<td>186.56</td>
<td>4</td>
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<tr>
<td>Oxytocin (mono-dose)</td>
<td>4,037</td>
<td>$6,628,359</td>
<td>$36,767</td>
<td>$9</td>
<td>180.28</td>
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<tr>
<td>Oxytocin (multi-dose)</td>
<td>4,037</td>
<td>$6,628,359</td>
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<td>Ergometrine</td>
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<td>Misoprostol (oral)</td>
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<tr>
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<td>$11</td>
<td>149.01</td>
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</table>

*Source: Seligman and Xingzhu.22
**Total disability-adjusted life years (DALYs).
***Unijet is a trademark of BD.

Gap analysis

WHO recommendation
For the class of products that would include NASGs, the global endorsement with the highest visibility is inclusion in the WHO Guidelines for the Management of Postpartum Hemorrhage and Retained Placenta. No data were available when the committee last convened to review these guidelines, so they decided not to make a recommendation until research results become available. It will be several years until WHO makes a recommendation on the NASG because the RCTs and data analysis must be completed beforehand. Results from the trials should be available in 2013.

Market effects
WHO will not list the NASG in the Interagency List of Essential Medical Devices for Reproductive Health until it has been included in the WHO guidelines mentioned above. Although inclusion of the NASG in this document is not mandatory for advancing procurement, it would add an additional and beneficial layer of endorsement from WHO and key partners. Preparing a proposal to include NASG in a future guideline update would require little investment, and successful inclusion would serve to expand awareness and subsequent uptake of the product among countries that use the guidelines to update national requirements for medical devices.

Distribution
Distributing the garment to low-resource settings remains an enormous challenge. PATH is currently working with manufacturers and logistics experts to develop an import, warehousing, and distribution strategy that will increase access in Africa.
Use logistics

Unsolved use-logistics hurdles include, for example, ensuring that each garment is returned for reuse (after cleaning) to the facility where it originated and accounting for the number of times each garment has been used.

Cleaning

A cleaning validation (i.e., research into the safest and most effective way to clean the garment) has not been performed. Anecdotal evidence indicates that up to five different cleaning regimens are currently in use. High concentrations of cleaning chemicals may be harmful to the durability of the neoprene.

Sizing

RCTs have been completed on the large-sized garment,\(^ {17,19}\) and a medium and small garment are also being used in smaller programs outside the clinical trials. Still, no succinct method of sizing has been demonstrated or communicated. This poses a challenge for both regulatory and purchasing agents.

Investment opportunity

Investments in the following activities may help bridge the gaps identified above, allowing the NASG to save the greatest number of lives possible. These activities should be coordinated through a consortium led by the following key stakeholders: Pathfinder International, PATH, and the University of California, San Francisco.

Prior to completing the RCTs:

- Identify and test alternate cleaning methods and stain-resistant spray-on coatings to identify one or more alternatives to high volume, water-based NASG cleaning methods that are currently seen as a barrier to compliance.

- Advance understanding of the physiology and function of the NASG, which can be used to improve the instructions for use, inform sizing guidelines, and focus future research to assist with use protocols.

  - Conduct a study (using uterine artery flow rate and abdominal pressure end points) to evaluate the efficacy of NASG as a function of body mass index (BMI)/abdominal girth of patients and the interaction between the patient BMI/girth and applier strength. These studies would be conducted on postpartum and otherwise healthy women following protocols similar to those already published by Suellen Miller.\(^ {18}\)

  - Conduct a small-, medium-, and large-size NASG study (using uterine artery flow rate and abdominal pressure end points) to evaluate the correlation between NASG size, anthropomorphic data, and function indicators.

- Increase evidence for cleaning and use logistics as well as instructions for use.

  - Contract a controlled laboratory bio-burden cleaning validation of three to five cleaning methods through North American Science Associates, Inc. (NAMSA), an independent regulatory group.\(^ {23}\)
Use NAMSA results to identify the most effective and least harmful method. Determine, via laboratory testing, the effective life of the NASG (40 wash cycles) using the chosen cleaning protocol.

– Identify or develop (if not commercialized) a tablet form of bleach solution that can be sold with the NASG or separately as a maintenance cost. Identify potential manufacturers and distributors of the cleaning tablets in India.

– Develop written instructions for use that include better graphics and instructions for applying, removing, and cleaning the garment.

• Build a network of import, warehousing, and distribution partners in areas of highest need (highest maternal mortality due to PPH) to enable affordable access.

Following completion and publication of the RCTs and validation of device effectiveness:

• Rigorously pursue global regulatory pathways, including seeking a strong recommendation (assuming RCT results warrant) in the WHO Guidelines for the Management of Postpartum Hemorrhage and Retained Placenta as well inclusion in the Interagency List of Essential Medical Devices for Reproductive Health.

• Rigorously pursue regional and national regulatory pathways, focusing on national regulatory registration and approval in select countries where the burden of maternal mortality is very high and where ministries of health are receptive to the introduction of the NASG (facilitated by existing and future AMTSL training programs).

• Build additional evidence for NASG use in a variety of diverse settings. Conduct an expanded use profile by means of a pilot study including data collection and evaluation of the use of the NASG by ambulance drivers or other workers.

• Additional activities should include advocacy, introductory pilot programs, scale-up, and subsidized supply.
References


